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COAGULATION FACTOR WORKING PARTY FOR SCOTLAND AND NORTHERN IRELAND

2003/2004

16th ANNUAL REPORT

Membership

The current members of the Working Party are:

Dr J Anderson
Dr P Cachia
Dr E Chalmers
Dr P Clark
Professor I M Franklin
Dr E H Horn
Professor G D O Lowe
Professor C A Ludlam (Chairman)
Dr W Murray
Miss J Pelly (Secretary)
Dr R J Perry
Dr C V Prowse
Dr C Tait
Dr A E Thomas
Professor I D Walker
Dr H G Watson

In attendance:

Mrs D Evans
Mr K Thompson
Dr A Keel

This year there have been four meetings of the Working Party.

Provision of Coagulation Factor Concentrates in Scotland and Northern Ireland

In Scotland and Northern Ireland all appropriate haemophilia patients are being offered recombinant factor VIII and IX concentrate and there are only a few patients who remain on plasma derived products, with for medical reasons or for patients personal preference. We continue to review the supply situation for recombinant factor VIII and to appraise SNBTS for any potential forecast increased need for plasma derived concentrate.

Factor VIII Concentrate

The recently developed Liberate HT (80^0C for 72 hours and solvent/detergent treated) awaits its product licence. The use of SNBTS plasma derived factor VIII concentrate in Scotland is small and is mainly for new patients with acquired haemophilia. SNBTS keep available a stock and the current estimate of potential annual use is 2 million units.

Factor IX Concentrate

SNBTS high purity factor IX concentrate (HIPFIX) has a product license, but as the majority of patients in Scotland are treated with recombinant factor IX concentrate the anticipated use in Scotland is small.

Prothrombin Complex Concentrates

SNBTS have now manufactured "clinical batches" of concentrate containing factors II, VII, IX and X. A protocol has been developed and agreed for clinical trial of this four factor concentrate for warfarin reversal. It is hoped that the trial will begin in the near future.

Fibrinogen Concentrate

The SNBTS fibrinogen concentrate continues under evaluation for the treatment of congenital hypofibrinogenaemia and acquired hypofibrinogenaemia in liver disease for patients undergoing hepatic biopsies.

vCJD and "Implicated Plasma Donation"

Issues related to vCJD have continued to be one of the principal agenda topics. In the absence of specific advice from the CJD Incidents Panel, Haemophilia Directors wrote to all patients with haemophilia in Scotland who were treated with factor VIII concentrate during the period of 1987-1989 about the three implicated batches of SNBTS factor VIII and IX given to patients. Since then the following have been the principal issues of concern:

- Publication in January 2004 of a possible case of vCJD transmission by red cell concentrate.
- CFWP has developed an agreed notification strategy should SNBTS be informed of further "implicated" plasma donations, which contributed to clotting factor concentrates (appended).
- Recently it has become apparent that there are additional implicated batches of BPL clotting factor concentrates, which have not been notified to Haemophilia Centres (used in England).
- The Health Protection Agency has taken over responsibility for developing a policy for "notifying" patients who received "implicated" blood products. Where as it has been decided to inform all recipients of fresh and cellular "implicated donations" (approximately 48 in the UK) no decision has been

reached about recipients of other materials e.g. clotting factor concentrates, immunoglobulin and albumin. A "risk assessment" has defined groups of recipients in to high, intermediate and low "risk" of receiving a dose of "vCJD" that would give a "1% risk" of transmission.

- Haemophilia Directors agree that it would be preferable to identify recipients "at risk" as those who have been treated with UK plasma products since 1980. Whilst this is a relatively simply way, and a less "threatening" way to identify patients, there will still be a need to inform those recipients who wish to know whether they have received "implicated batches" and if so what quantity. This is potentially a huge logistic exercise for England considering the time it took to identify recipients in Scotland at six haemophilia centres who received three batches.
- The ACDP has given advice on "decontamination" of surgical instruments when used on individuals who may have received "implicated" blood products. The principal restrictions relate to CNS and lymphoid surgery. The main outstanding issue is how endoscopes should be decontaminated if a gut biopsy is taken. This has very important implications for patients with haemophilia.
- The HPA is leading the process of developing a policy and arrangements for informing haemophilia centre directors and subsequently patients about vCJD. This is being assisted by liaison with UKHCDO. Haemophilia Directors are very concerned about the slow progress being made in developing both a policy for informing patients and for implementing appropriate public health safety measures. In Scotland discussions will take place with SCIEH, SNBTS and Haemophilia Directors about the most appropriate further arrangements for contacting patients.
- UKHCDO has plans and funding to develop a vCJD surveillance project. This will require further resource because of the large number of BPL implicated batches.
- The CFWP is keen to see a early co-ordinated arrangement for keeping patients informed about issues related to vCJD as well as the implementation of appropriate public health safety measures.

Recombinant VIIa (NovoSeven)

Whereas the major use of recombinant VIIa is for treatment of individuals with haemophilia A with anti factor VIII antibodies there is a small use for treating patients with life threatening haemorrhage unresponsive to other therapies. A protocol has been developed for recombinant VIIa use in non-haemophiliacs with life threatening bleeds and an audit has been established to monitor its use and clinical outcome. Currently this is being undertaken at teaching hospitals with haemophilia centres in Scotland. It is hoped to roll out the audit with the Scottish Haematology Society to all hospitals in Scotland as recombinant VIIa is widely used in many hospitals.

Acknowledgement

As ever Jane Pelly has provided most efficient and effective support.

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